

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors:

Ghai et al.

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Art Unit:

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August 15, 2002

Examiner: Kailash C. Srivastava

For:

EXTRACTS OF ORANGE PEEL

Attorney Docket No.: 11592-006-999

FOR PREVENTION AND

(formerly RU-0103-US

TREATMENT OF CANCER

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.56 AND §1.97

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and § 1.97 to inform the Patent Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby invite the Examiner's attention to the references A01-A07, B01-B29 and C01-C53 listed on the attached revised form PTO 1449 entitled "List of References Cited by Applicant." Copies of references B01-B29 and C01-C53 are submitted herewith.

Identification of the listed references is not meant to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application. Consequently, Applicants respectfully decline to use form PTO-1449, since this form identifies all of the references cited therein as "Prior Art." As an alternative, Applicants submit herewith a "revised form PTO 1449" entitled "List of References Cited" instead of "List of Prior Art Cited".

Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the application.

Since this Supplemental Information Disclosure Statement is being filed in the United States Patent and Trademark Office concurrently with a Request for Continued Examination under 37 C.F.R. § 1.114, pursuant to 37 C.F.R. § 1.97(b)(4), Applicants believe that no fee is

due. However, should the Patent and Trademark Office determine otherwise, please charge any required fee to Jones Day Deposit Account No. 50-3013. A duplicate of this sheet is enclosed for accounting purposes.

Date May 11, 2005

Respectfully submitted,

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Sheet 1 of 3

LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO. 11592-006-999 APPLICATION NO. (formerly RU-0103-US) 10/088,664 APPLICANT Ghai et al. GROUP FILING DATE August 15, 2002 1651

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	3,867,541	02/18/1975	Robbins			
	A02	3,903,266	09/02/1975	Robbins			
	A03	5,041,425	08/20/1991	Hasegawa et al.			
	A04	6,184,246	02/06/2001	Manthey et al.			
	A05	6,221,357	04/24/2001	Bok et al.			
	A06	6,239,114	05/29/2001	Guthrie et al.			
	A07	6,251,400	06/26/2001	Guthrie et al.			

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSL	ATION
							YES	NO
	B01	CN 1049340	02/20/1991	China (with English abstract)				
	B02	CN 1069200	02/24/1993	China (with English abstract)				
	B03	CN 1071576	09/26/2001	China (with English abstract)				
	B04	CN 1094957	11/16/1994	China (with English abstract)				
	B05	CN 1100322	03/22/1995	China (with English abstract)				
	B06	CN 1105853	08/02/1995	China (with English abstract)				
	B07	CN 1108554	09/20/1995	China (with English abstract)				
	B08	CN 1139007	01/01/1997	China (with English abstract)				
	B09	CN 1145804	03/26/1997	China (with English abstract)				
	B10	CN 1170592	01/21/1998	China (with English abstract)				
	B11	CN 1191746	03/05/1998	China (with English abstract)				
	B12	CN 1279905	01/17/2001	China (with English abstract)				
	B13	CN 1301507	07/04/2001	China (with English abstract)				
	B14	DE 39 22 666	07/10/1989	Germany (abstract see A03)				
	B15	JP 2000-80035	03/21/2000	Japan (with English abstract)				
	B16	JP 2000-83654	09/14/1998	Japan (with English abstract)				
	B17	JP 2004-137218	05/13/2004	Japan (with English abstract)				
	B18	JP 3010210	12/10/1999	Japan (with English abstract)				
	B19	JP 60-199817	10/09/1985	Japan (with English abstract)				
	B20	JP 9-295932	11/18/1997	Japan (with English abstract)				
	B21	WO 1999/15167	04/01/1999	PCT (U.S.)				
	B22	WO 1999/52380	10/21/1999	PCT (Korea)				
	B23	WO 1999/62358	12/09/1999	PCT (Korea)				<u> </u>
	B24	WO 2000/07607	02/17/2000	PCT (U.S.)				

010	B25	WO 2000/32062	06/08/2000	PCT (Israel)		
U. F.	B26	WO 2000/64282	11/02/2000	PCT (Italy)		
May	B ₂ 7	WO 2000/76492	12/21/2000	PCT (U.S.)		
AY 1 1 2005	B28	WO 2001/51043	07/19/2001	PCT (U.S.)		
P A STANKE	B29	WO 2001/70029	09/27/2001	PCT (U.S.)		

MADEMARY	OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)
C01	Two 1
 	(7 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
C02	• • • • • • • • • • • • • • • • • • • •
C03	
C04	204:P184-AGFD (1992) [abstract]
C05	Clinica Belgica 54(2):109 (1999) [abstract]
C06	Bracke et al., "Citrus flavonoid effect on tumor invasion and metastasis the citrus flavonoid tangeretin may inhibit the processes that shorten the life expectancy of tumor-bearing patients," Food Technology, Institute of Food Technologists, Chicago, US, 48(11):121-124 (1994)
C07	- 1 1 1 C 1 C 1 C 1 C 1 C 1 C 1 C 1 C 1
C08	D 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
C09	Bracke et al., "The flavonoid tangeretin inhibits invasion of MO ₄ mouse cells into embryonic chick heart in vitro," Clin. Expl. Metastasis 7(3):283-300 (1989)
C10	D. I. and M. C. and M. C. and M. C. and C. a
CII	D 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
C12	To the transfer of the state of
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C18	Deschner et al., "Quercetin and rutin as inhibitors of azoxymethanol-induced colonic neoplasia," Carcinogenesis 12(7):1193-1196 (1991)
C19	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
C20	CTT - (711 1 1 1 1 1 C 1 1 1 1 C 1 1 1 T T T T T
C21	Guthrie and Carroll, "Inhibition of human breast cancer cell growth and metastasis in nude mice by citrus juices and their constituent flavonoids," <i>Biological Oxidants and Antioxidants: Molecular Mechanisms and Health Effects</i> , edited by Lester Packer and Augustine S.H. Ong, Aocs Press, Champaign, Illinois, Chapter 35 pp. 310-316 (1998)
C22	Mantey and Buslig, Plenum Press, New York, Chapter 16 227-236 (1998)
C23	
C24	Guthrie et al., "Combined effects of palm oil tocotrienols, flavonoids and tamoxifen on the proliferation of estrogen receptor-positive MCF-7 human breast cancer cells," <i>Proceedings of the American Association for Cancer Research</i> 37:280 (1996)
C2:	Guthrie et al., "In vitro studies on anti-cancer and cholesterol-lowering activities of citrus flavonoids and limonoids," FASEB Journal, Fed. of American Soc. For Experimental zBiology, BVethesda, MD, US 14(15):A563 (Mar. 2000)
C20	TT 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
C27	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1

Hunchong, "Origin confirmation of a new natural product from Oldenlandia diffusa," Journal of Chinese Medicinal Materials 21(6):301-302 (1998) [Chinese w/English abstract] Iwase et al., "Inhibitory effect of flavonoids from Citrus plants on Epstein-Barr virus activation and two-stage carcinogenesis of skin tumors," Cancer Letters 154:101-105 (2000) Kandaswami et al., "Antitproliferative effects of citrus flavonoids on a human squamous cell carcinoma in vitro," C30 Cancer Letters 56:147-152 (1991) Kandaswami et al., "Differential inhibition of proliferation of human squamous cell carcinoma, gliosarcoma and C31 embryonic fibroblast-like lung cells in culture by plant flavonoids," Anti-Cancer Drugs 3:525-530 (1992) Kawai, "Physiology of Fruits Juice: Cancer Retardant/Inhibitor in Citrus Juice" Shokuhin Kogyo pp35-43, June 2000 C32 Kawaii et al., "Antiproliferative activity of flavonoids on several cancer cell lines," Biosci. Biotechnol. Biochem. C33 63(5):896-899 (1999) Kawaii et al., "Effect of citrus flavonoids on HL-60 cell differentiation," Anticancer Research 19:1261-1269 (1999) C34 Kawaii et al., "Quantitation of flavonoid constituents in Citrus fruits," J. Agric. Food Chem. 47:3565-3571(1999) [In C35 Japanese, no English abstract available at time of filing] Kinoshita et al., "Differentiation induction of murine leukemia cells by flavonoids," J. Pharmacobio-Dyn. 8:s-122 C36 (1985)Kinoshita et al., "Induction of differentiation in murine erythroleukemia cells by flavonoids," Chem. Pharm. Bull. C37 33(9):4109-4112 (1985) Lake et al., "Inhibition of xenobiotic-induced genotoxicity in cultured precision-cut human and rat liver slices," C38 Mutation Research 440:91-100 (1999) Le Bon et al., "Inhibition of microsome-mediated binding of benzo[alpha]pyrene to DNA by flavonoids either in vitro C39 or after dietary administration to rats," Chem.-Biol. Interacations 83:65-71 (1992) Malterud, "Flavonoids from Orthosiphon spicatus," Planta Medica 55:569-570 (1989) C40 Manthey et al., "Biological properties of citrus flavonoids pertaining to cancer and inflammation," Current Medicinal C41 Chemistry 8:135-153 (2001) Manthey et al., "Methoxylated citrus flavones suppress cytokine expression by monocytes," Abstracts of Papers C42 American Chemical Society 217(1-2):pMEDI 212 (1999) [abstract] Manthey et al., "Polymethoxylated flavones derived from citrus suppress tumor necrosis factor-alpha expression by C43 human monocytes," J. Nat. Prod. 62:441-444 (1999) Middleton and Kandaswami, "Potential health-promoting properties of citrus flavonoids," Food Technology pp. 115-C44 119 (Nov. 1994) Murakami et al., "Inhibitory effect of citrus noiletin on phorbol ester-induced skin inflammation, oxidative stress, and C45 tumor promotion in mice," Cancer Research 60:5059-5066 (2000) Murakami et al., "Suppressive effects of citrus fruits on free radical generation and nobiletin, an anti-inflammatory C46 polymethoxyflavonoid," BioFactors 12:187-192 (2000) Rooprai et al., "Influence of putative antiinvasive agents on matrix metalloproteinase secretion by human neoplastic C47 glia in vitro," Annals New York Academy of Sciences 878:654-657 (1999) Rouseff and Nagy, "Health and nutritional benefits of citrus fruit components," Food Technology 125-126, 128-C48 129,132 (Nov. 1994) Siess et al., "Mechanisms involved in the chemoprention of flavonoids," BioFactors 12:193-199 (2000) C49 So et al., "Inhibition of human breast cnacer cell proliferation and delay of mammary tumorigenesis by flavonoids and C50

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*EXAMINER		DATE CONSIDERED if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not
	C53	Vines, "Fruity formula could contain prostate cancer (Possible oral medication for containing prostate cancer)," New Scientist p. 18 (1995)
	C52	Tsuchiya and Yamane, "Cotransport of Na+ and amino acids in Escherichia Coli," J. Pharmacobio-Dyn. 8:s-124 (1985)
	C51	Soma et al., "Regulation of gene expression during redifferentiation of promoyelocytic leukemia cells HL-60 by 12-O-tetradecanoylphorbol-13-acetate," <i>J. Pharmacobio-Dyn.</i> 8:s-123 (1985)
		citrus juices," Nutrition and Cancer 26(2):167-181 (1996)